JUL - 1 2011

SECTION 10
510(K) PREMARKET NOTIFICATION SUMMARY

SUBMITTER'S NAME AND ADDRESS: MATERIALISE DENTAL NV
Technologielaan 15
B-3001 LEUVEN, BELGIUM

ESTABLISHMENT REGISTRATION NO: 3006638827

CONTACT PERSON: Peter Vandeput, Materialise Dental NV
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SUMMARY PREPARATION DATE: November 15, 2010

TRADE NAME: SimPlant 2011

COMMON NAME:

Image processing system and preoperative software for simulating /evaluating dental implant placement and surgical treatment options

CLASSIFICATION NAME:

System, Image Processing. This product uses images acquired from Computerized Tomography (CT) scanners.

PREDICATE DEVICE: SimPlant Dr James (K053592)

FUNCTION

The modified SimPlant System is used to transfer images from a medical scanner and to perform a segmentation of the images. It is also used to provide a means for pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning.

INTENDED USE

SimPlant 2011 is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

TECHNOLOGICAL COMPARISON OF DEVICES

Feature	SimPlant 2011	SimPlant System
Material	Software – magnetic media	Software – magnetic media
Design	Software for use in pre-operative planning. - Volume Rendering ▪ Direct Volume Rendering ▪ ISO Surface ▪ X-Ray Rendering ▪ Maximum Intensity Projection Rendering ▪ 16bit compatibility - Segmentation Wizard - Reorient axial images to occlusal plane - Advanced virtual teeth - Advanced grafts and Volumes - Dual scan registration - Optical scan registration ▪ Optical Scannner support ▪ Optical scan for .sim files - Occlusion tool - Virtual occludator - Advanced Soft tissue simulation ▪ OMS-3D Photomapping - Surgical Guide Wizard	Software for use in pre-operative planning. - Volume Rendering ▪ Direct Volume Rendering ▪ No ISO Surface ▪ No X-Ray Rendering ▪ No Maximum Intensity Projection Rendering ▪ 16bit compatibility - No Segmentation Wizard - No Reorient axial images to occlusal plane - Virtual teeth - Grafts and Volumes - No dual scan registration - No optical scan registration ▪ No Optical Scannner support ▪ No Optical scan for .sim files - No occlusion tool - No virtual occludator - Soft tissue simulation ▪ No OMS-3D Photomapping - Surgical Guide Wizard
Function	**SimPlant 2011** provides a means for transferring patient images from a medical scanner to an output file. **SimPlant 2011** is used to provide a means for advanced pre-operative planning of dental implant placements and orthognatic treatment. **SimPlant 2011** is used to provide a means for image segmentation. **SimPlant 2011** contains a library of dental implants. Surgical templates may be designed and fabricated based on the output of the pre-operative planning.	**SimPlant system** provides a means for transferring patient images from a medical scanner to an output file. **SimPlant System** is used to provide a means for pre-operative planning of dental implant placements and orthognatic treatment. **SimPlant System** is used to provide a means for image segmentation. **SimPlant** contains a library of dental implants. Surgical templates may be designed and fabricated based on the output of the pre-operative planning.

Non-clinical testing and software validation

The SimPlant 2011 software originates from the same medical software platform as the SimPlant system marketed by Materialise Dental and cleared under K033849.

Thorough testing has been performed. This software product does not contact the patient and does not deliver medication or therapeutic treatment.

For the SimPlant software, non-clinical testing was performed, in accordance with the following Standards:

- ISO 13485:2003 Medical devices - Quality Management Systems.
- IEC 62304:2006 Medical device software – Software life cycle processes
- EN ISO standard 14971:2007 Medical Device – Application of risk management to devices.

The SimPlant software is tested in accordance with a documented test plan. This test plan is derived from the final specifications and ensures that all controls and procedures are functioning properly. It defines what is to be accomplished through the software validation effort. The testing of the software typically consists of Unit testing, Integration testing, IR testing, Smoke testing, different types of Formal testing (General testing, Functional testing, Reference testing, Usage testing), Acceptance testing, Alpha testing and Beta testing.

The tests are intended to establish how the software reacts to usual inputs and to unexpected or invalid inputs (verifying robustness). Software testing includes both static and dynamic analysis of the software. Static evaluation techniques include inspections, walkthroughs, etc. and are intended to find, correct and prevent problems in an early stage of the development process. They are used to focus or augment dynamic analysis, which is concerned with demonstrating the software's run-time behavior in response to selected inputs and conditions.

The results of the complete testing are on file in the offices of Materialise Dental and are contained within the Design History File.

CONCLUSION

The modified SimPlant 2011 is considered to be substantially equivalent in design, material and function to the unmodified SimPlant (Dr. James). It is believed to perform as well as the predicate device for pre-operative planning and for image segmentation. Accordingly, we respectfully request the Agency to expeditiously find this special 510(k) premarket notification to be Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL - 1 2011

Mr. Peter Vandeput
Quality Manager, Regulatory Affairs Representative
Materialise Dental NV
Technologietaan 15, 3001 Leuven
BELGIUM

Re: K110300
Trade/Device Name: SimPlant 2011
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 21, 2011
Received: June 23, 2011

Dear Mr. Vanderput:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110300

Device Name: SimPlant 2011

Indications for Use:

SimPlant 2011 is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110300